UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: BeWanda Alexander

From: Kevin Sweeney

Date: December 8, 2011

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 395909
Decision no.: 455549
Submission no: 904234
Action code: 570
Product Name: SiliCide
EPA Reg. No or File Symbol: 73079-12
Formulation Type: RTU Dust
Ingredients statement from the label with PC codes included: 100% Silicon dioxide (PC code 072605)
Application rate(s) of product and each active ingredient: 2 oz./100 square feet

I. **Action Requested:** review response to DER dated July 26, 2011 and to Agency's NOR dated July 28, 2011

II. **Background:** Registrant submitted an application for a silicon dioxide (Amorphous silica gel) product to include bed bugs. Bed bugs were not listed on the cited label. The registrant submitted a study to evaluate the efficacy of the active ingredient against bed bug adults, nymphs and eggs. The study was reviewed and evaluated in light of the submitted labeling and associated use pattern. The Agency requested the registrant to remove a: "Kills resistant bed bugs" claim; the high application rate of 1 pound/250 square feet; and to provide supporting information on the origin and characteristics of the pyrethroid resistant Epic center strain.

III. **An MRID was not submitted but the registrant provided a written response to each of the Agency's comments.**

- Retain the claim: "Kills pyrethroid resistant bed bugs" based on the difference between the modes of action of silica dioxide (a desiccant) and pyrethroid insecticides (neural toxins).
- Retain the high application rate because the cited product included this application rate and the cited and subject products were substantially similar.
- Reorganized the label's directions for use.
- A description of the development and maintenance of the pyrethroid resistant Epic Center bed bug strain. Resistance ratios (based on LT_{50} values derived from continuous exposure to the label rate applied to unpainted hardwood) were provided for three pyrethroid insecticides(β-cyfluthrin, bifenthrin and deltamethrin). A Probit Analysis was used to determine the LT values.

IV. ENTMOLOGIST'S RECOMMENDATIONS:

1. The revised label is acceptable.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID: 483474-01; McCoy, T.C., Silica Dust Formulation Efficacy for Control of Bed Bugs (*Cimex lectularius*), September 10, 2010.

No guideline exists for bed bugs

Product Name: SiliCide™
EPA Reg. No. or File Symbol: 73079-RE
Decision number: 444104
DP number: 387010

Prepared for
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec
Task Order No.: 2-07

Primary Reviewer:
Robert Ross, M.S.

Signature: Robert H. Ross
Date: JUL 25 2011

Secondary Reviewer:
Gene Burgess, Ph.D.

Signature: for Gene Burgess
Date: JUL 25 2011

Program Manager
Robert Ross, M.S.

Signature: Robert H. Ross
Date: JUL 25 2011

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: JUL 25 2011

RECOMMENDED CLASSIFICATION: **Unacceptable, but upgradable**

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE [No guideline No.]
MRID:	**483474-01; McCoy, T.C., Silica Dust Formulation Efficacy for Control of Bed Bugs (*Cimex lectularius*), September 10, 2010.**
DP BARCODE:	**387010**
DECISION NO:	**444104**
SUBMISSION NO:	888576
SPONSOR:	Rockwell Labs Ltd., 1512 Taney St., North Kansas City, MO, 64116
TESTING FACILITY:	Department of Entomology, Virginia Tech, Blacksburg, VA, 24061
STUDY DIRECTOR:	Dini M. Miller, Ph.D.
SUBMITTER:	Cisse Spragins, Ph.D., Rockwell Labs Ltd., 1512 Taney St., North Kansas City, MO, 64116
STUDY COMPLETED:	10/09/2010
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	Not conducted according to GLP 40 CFR Part 160 EPA (FIFRA)
TEST MATERIAL:	PRODUCT NAME: SiliCide™ EPA REGISTRATION NUMBER OR FILE SYMBOL: 73079-RE ACTIVE INGREDIENT NAME: Amorphous Silica Gel CHEMICAL NAME: Silicon dioxide A.I. %: 100 PC CODE: 072605 CAS NO.: 7631-86-9 FORMULATION TYPE: Dust PRODUCT APPLICATION RATES g/m^2: 2 oz/100 ft^2 (6.1 g/m^2, reviewer calculated); 1 lb/1000 ft^2 (4.9 g/m^2, reviewer calculated)

ACTIVE INGREDIENT APPLICATION RATE(S)g/m^2: same as product

PROPOSED LABEL MARKETING CLAIMS: Bed Bugs

EPA REQUESTS:

[EPA WILL ADD DIRECTIVES HERE]

STUDY REVIEW

Study Number/Title: (if more than one study is provided in the MRID)

Purpose: To test the efficacy of silica dust against bed bug adults, nymphs, and eggs.

MATERIALS AND METHODS

Test Location: Dodson Urban Pest Management Laboratory at Virginia Tech University, Blacksburg, VA.

Test Material(s): The test material was amorphous silica gel applied at the label rate of 2 oz/100 ft^2 and
2 oz/1000 ft^2 (The 2 oz/ 1000 ft^2 rate was not listed on the label and may be a typographical error.) The reviewer does not know if the material is the same as the EPA product or file symbol.

Test Species Name, Life Stage, Sex and Age: Adult, nymphs (3-5^{th} instars), and eggs of Epic Center strain bed bugs (*Cimex lectularius*).

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted:

Petri dishes (9.5 cm dia.) containing either adult or nymphs were inverted onto hardwood panels which had been pre dusted with the test material (2 oz/100 ft^2). The eggs were deposited on filter paper discs (4.25 cm dia.) and then dusted with silica dust at 2 oz/1000 ft^2 (This application rate is not mentioned on the label, but this value may actually be 1 lb/1000 ft^2 which is on the label). The adults and nymphs were evaluated for mortality at 1, 2, 4, 5, 6, 8, 10, 12, and 15 hours following continuous exposure. After the eggs were dusted by brush with silica dust, observations of hatching and mortality after hatching were observed for 8 days.

List the treatments including untreated control (express application rate as g/m^2): For tests on adults and nymphs, the text on page 5 indicates that control tests were conducted but the results were not given. Control results were given in a figure for hatching of untreated eggs. The application rate was 6.1 g/m^2 for adults and nymphs and 0.6 g/m^2 for eggs if this indeed was the actual exposure (see above paragraph).

Number of replicates per treatment: four

Number of individuals per replicate: 10 adults and 10 nymphs; groups of bed bug eggs

Length of exposure to treatment (time in seconds, minutes or hours): Continuous exposure for 15 hours in tests with adults and nymphs and 8 days of continuous for eggs and nymphs that hatched.

Experimental conditions (state relative humidity, temperature, and photoperiod): Not given for test environments, but while being reared for testing, rearing jars kept at 27°C, 55 % RH, and 12:12 photoperiod.

State data or endpoints that were to be collected/recorded: Mortality for adults and nymphs and hatchability for eggs followed by mortality for nymphs that hatched.

Were the data analyzed? If so, what statistical analyses were performed?

Yes, but method not stated. As mentioned earlier, no comparisons with control test were presented for Petri dish testing of adults and nymphs although the text in the study report says that control tests were performed.

RESULTS

Tables 1 and 2 show the LT_{50} and LT_{90} values respectively for adult and nymphs. For adults, 100 % mortality was achieved by 15 hours and for nymphs, by 10 hours. Treatment did not have any effect on egg hatchability (at day 8, 97 % hatched compared to control value of 99 %), but did cause 68 % mortality by day 4 and 100 % by day 8 of the nymphs that hatched. Raw data were presented with the exception of the control data for the Petri dish experiments preventing the use of Abbott's formula. However the control data presented with the egg test does show the expected results.

Table 1. Comparison of LT_{50} values calculated for pyrethroid resistant bed bugs (Epic center strain) confined on hardboard panels dusted with silica dust (9.5 cm dia treatment area) at the rate of 2oz/100 sq. ft. (n = 4 replicates).

Treatment	N	LT_{50} (hours)	95% CIs	Slope ± SE
Adults	40	9.3a	8.6 – 10.2	0.32 ± 0.3
Nymphs	40	4.3b	3.8 – 4.8	0.43 ± 0.05

Values followed by the same letter are not significantly different at p=0.05

Table 2. Comparison of LT_{90} values calculated for pyrethroid resistant bed bugs (Epic center strain) confined on hardboard panels dusted with silica dust (9.5 cm dia treatment area) at the rate of 2oz/100 sq. ft. (n = 4 replicates).

Treatment	N	LT_{90} (hours)	95% CIs	Slope ± SE
Adults	40	13.3a	12.2 – 15.1	0.32 ± 0.3
Nymphs	40	7.3b	6.6 – 8.2	0.43 ± 0.05

Values followed by the same letter are not significantly different at p=0.05

Study Authors Conclusions

No conclusions were presented, but the data support the submitter's addition of bed bugs to the label.

Reviewers Conclusions

Control mortality data were not available for the Petri dish experiments, but the mortality from the egg hatchability study gave the expected results. As noted above, the results of the experiments support the addition of bed bugs to the label once deficiencies listed below are addressed.

Reviewer Recommendations

The study is not acceptable, but can be upgraded to acceptable if (1) the control data are provided for the Petri dish experiments and (2) clarification is provided regarding the label application

rates versus the test application rates. The rate of 2 oz/1000 ft^2 used in the egg hatchability test is not mentioned on the label and could be a typographical error. The addition of bed bugs to the label is supported by the data once the deficiencies are addressed. Also, the label should provide more details when and on what pests the different application rates apply.

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List the treatments including untreated control (express application rate as g/m^2): For tests on adults and nymphs, the text on page 5 indicates that control tests were conducted but the results were not given. Control results were given in a figure for hatching of untreated eggs. The application rate was 6.1 g/m^2 for adults and nymphs and 0.6 g/m^2 for eggs if this indeed was the actual exposure (see above paragraph).

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Number of individuals per replicate: 10 adults and 10 nymphs; groups of bed bug eggs

Length of exposure to treatment (time in seconds, minutes or hours): Continuous exposure for 15 hours in tests with adults and nymphs and 8 days of continuous for eggs and nymphs that hatched.

Experimental conditions (state relative humidity, temperature, and photoperiod): Not given for test environments, but while being reared for testing, rearing jars kept at 27°C, 55 % RH, and 12:12 photoperiod.

State data or endpoints that were to be collected/recorded: Mortality for adults and nymphs and hatchability for eggs followed by mortality for nymphs that hatched.

Were the data analyzed? If so, what statistical analyses were performed?

Yes, the adult and nymphal assays were analyzed using a Probit analysis. The egg data were described based on % hatch and % mortality. The untreated control in the egg assay had 0% mortality. As mentioned earlier, no comparisons with control test were presented for Petri dish testing of adults and nymphs although the text in the study report says that control tests were performed.

RESULTS

Tables 1 and 2 show the LT_{50} and LT_{90} values respectively for adult and nymphs. For adults, 100 % mortality was achieved by 15 hours and for nymphs, by 10 hours. Treatment did not have any effect on egg hatchability (at day 8, 97 % hatched compared to control value of 99 %), but did cause 68 % mortality by day 4 and 100 % by day 8 of the nymphs that hatched. Raw data were presented with the exception of the control data for the Petri dish experiments preventing the use of Abbott's formula. However the control data presented with the egg test does show the expected results.

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Values followed by the same letter are not significantly different at p=0.05

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Adults	40	13.3a	12.2 – 15.1	0.32 ± 0.3
Nymphs	40	7.3b	6.6 – 8.2	0.43 ± 0.05

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Study Authors Conclusions

No conclusions were presented, but the data support the submitter's addition of bed bugs to the label.

Reviewers Conclusions

Control mortality data were not available for the Petri dish experiments, but the mortality from the egg hatchability study was 0%..

Reviewer Recommendations

The study is acceptable, but (1) the untreated control data should have been provided for the Petri dish experiments and (2) clarification should be provided regarding the label application rates versus the test application rates. The rate of 2 oz/1000 ft^2 used in the egg hatchability test is not mentioned on the label and could be a typographical error. Also, the label should provide more details when and on what pests the different application rates apply.